379.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,124	02/21/2002	Vivien Chan	PP-016336.002	8573

7590 08/04/2004

Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662

EXAMINER	
SMITH, CAROLYN L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,124	CHAN ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1 page*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Sequence Match Listing (1 page).

DETAILED ACTION

Applicants' election without traverse of Group I (claims 1-5), sequence election of SEQ ID NO: 489, election of Specie A (a gene product which is a nucleic acid), cancellation of claims 6-23 and amending of claim 1, filed 3/4/04, are acknowledged. Claim 3 is withdrawn as being drawn to a non-elected specie.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to gene products differentially expressed in cancerous colon cells and their methods of use, whereas in contrast the elected claims are specifically directed to a method for detecting a cancerous colon cell.

The information disclosure statement, filed 7/6/04, has been considered by the Examiner.

Claims herein under examination are 1, 2, 4, and 5.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1 (line 6) recites the term "probe" twice and the second mentioned "probe" is vague and indefinite. While the first mentioned probe in line 6 refers to the probe previously mentioned in line 2, it is unclear as to whether the second mentioned probe of line 6 is the same type of probe or a different probe than the first mentioned probe of line 6. Clarification of the metes and bounds of this term via clearer claim wording is requested. Claims 2, 4, and 5 are also rejected due to their dependency from claim 1.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by King et al. (WO 02/12328).

King et al. disclose a method for diagnosing colon cancer via the presence of tumor cells confirmed by predetermined differential expression levels (title and page 123, lines 25-29). King et al. disclose SEQ ID NO: 489 whose fragment from 1-323 which is a 100% match with a fragment of SEQ ID NO: 489 of the instant application (nucleotide positions 139-461) (see attached Sequence Match Listing sheet). King et al. disclose their invention includes

polynucleotide fragments to one or more sequences disclosed therein (page 63, lines 17-20). The instant specification states that "differentially expressed polynucleotides" encompasses fragments of the disclosed polynucleotides (page 8, paragraph 0025). Therefore, the fragment disclosed by King et al. represents a gene product. King et al. disclose their polynucleotide sequences can be used as probes for nucleic acid hybridization (page 69, lines 23-25 and page 70, lines 27-28). King et al. disclose using a hybridization probe to allow formation of duplex molecule that is both stable and selective (page 70, lines 19-20) which represents contacting and binding of the probe to the other product. King et al. disclose a polynucleotide may be identified by screening a microarray of cDNAs (gene products immobilized on an array) for tumor-associated expression, such as expression that is at least two fold greater in a tumor than in normal tissue (page 79, lines 11-14 and page 134, lines 14-20 and 30-31) which represents performing an assay on cancerous genes that are differentially expressed. King et al. disclose polynucleotides may be amplified from cDNA prepared from tumor cells (page 79, lines 18-19) which represents a sample obtained from a cell. King et al. disclose detecting cancer in a patient by determining the presence of one or more polynucleotides in a biological sample (i.e. tumor biopsy) (page 123, lines 13-16). King et al. disclose using polynucleotide probes to detect the level of mRNA which is indicative of the presence or absence of cancer (page 123, lines 21-23) which represents a cancerous state of the patient (including colon cell). King et al. disclose the tumor sequence should be present at a level that is at least two-fold in the tumor tissue than in normal tissue of the same type from which the tumor arose (page 123, lines 23-25) which represents a comparison of binding level of the probe to the sample with the level of probe binding to a control sample wherein the control colon cell is of known cancerous state (i.e. no

cancer). The "at least two-fold" disclosed above represents an increased binding level relative to the control indicating a cancerous sample. King et al. disclose other diagnostic purposes such as overexpression of a tumor sequence in tumor tissue and normal tissue of the same type, but not in other normal tissue types (page 124, lines 1-4). King et al. disclose an assay with a binding agent immobilized on a solid support (i.e. microtiter plate) (page 124, lines 18-20 and page 125, lines 3-11) which represents a probe immobilized on an array, as stated in instant claim 5. King et al. disclose incubating a detection reagent with a complex for an amount of time sufficient for detection (page 126, lines 28-31). King et al. disclose using markers for the progression of cancer and evaluating the change of polynucleotide levels over time (page 131, lines 25-31). King et al. disclose contacting tumor cells with a binding agent (i.e. polynucleotide probes) for detection (page 132, lines 3-7).

Thus, King et al. anticipate the limitations in claims 1, 2, 4, and 5.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

July 27, 2004

ARDIN H. MARSCHEL
PRIMARY EXAMINER

8/2/04